OBJECTIVES: Multiple sclerosis (MS) and Alzheimer's Disease (AD) are chronic and progressive diseases that have the potential to impose a significant burden on both caregivers and the immediate families of patients. Extensive literature has documented MS and AD caregiver burden on physical and mental health; but there are no direct comparisons of MS and AD caregivers. This study examined the extent of MS caregiver burden compared to non-caregivers and caregivers of AD patients. **METHODS:** Data were obtained from the 2009 National Health and Wellness Survey administered online to a US representative adult sample (N=75,000). Respondents reported health status, quality of life, work productivity, healthcare utilization and caregiver status. Multivariable regressions, adjusting for key characteristics (e.g., age, gender, marital status, depression), were conducted to explore differences between MS caregivers (n=215) vs. non-caregivers (n=69,224), as well as MS caregivers vs. AD caregivers (n=1,341). Rate ratios (RR) and regression weights (b) are reported. **RESULTS:** Compared to non-caregivers, MS caregivers had significantly greater activity impairment (RR=1.41; p=0.01) and poorer mental (b=−1.44; p=0.015), physical (b=−1.96; p=0.002), and health utility scores (b=−0.03; p=0.002), along with more traditional healthcare provider visits (RR=1.46; p<0.0001), ER visits (RR=2.16; p<0.0001), and hospitalizations (RR=2.20; p=0.001) after covariate adjustment. Compared to AD caregivers, MS caregivers had greater activity impairment (RR=1.29; p=0.044) and more ER visits (RR=1.60; p=0.017) and hospitalizations (RR=1.92; p=0.008) after covariate adjustment. Work productivity differences were not observed in comparison with either group, potentially due to the small number of employed MS caregivers in the sample (n=126). **CONCLUSIONS:** MS caregivers had significantly more burden compared with non-caregivers. In addition, the results suggest an even greater burden to these individuals than observed among AD caregivers. The results of this analysis of a national survey reveal the hidden toll of those providing care for MS patients and highlights the need to recognize their burden so that appropriate measures can be implemented.

PND39

MULTIPLE SCLEROSIS PATIENTS REPORT IMPROVEMENTS IN FATIGUE AND COGNITIVE FUNCTIONING AFTER ONE YEAR OF NATALIZUMAB TREATMENT

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OBJECTIVES: To evaluate changes in patient reported fatigue and cognitive function after one year of natalizumab treatment in multiple sclerosis (MS) patients. **METHODS:** The study population consists of MS patients initiating natalizumab treatment who agreed to participate in a 12 month longitudinal study. Patients reported experiences with natalizumab using validated patient-reported outcome (PRO) measures prior to natalizumab treatment initiation (BL) and after 3rd, 6th and 12th infusion. The current analysis reports change in fatigue and cognition from baseline through the 12th natalizumab infusion. Fatigue was measured by the 5-question Modified Fatigue Impact Scale-5 (MFIS-5, score range 0-20) with lower scores indicating lower impact of fatigue on physical, cognitive, and psychosocial functioning; cognitive function was measured by the 6-question Medical Outcomes Study Cognitive Functioning Scale (MOS-Cog Scale, score range 6-36) with higher scores indicating better reasoning skills, memory, concentration, ability to start several actions at one time and ability to react to what is said or done. Regression analysis was used to control for BL covariates such as age, years since MS diagnosis, number of natalizumab infusions received, disability and functional status, number of MS drugs used prior to natalizumab and comorbidity burden. **RESULTS:** Data for 324 patients who completed the BL through 12th infusion assessments are reported. The mean age was 46.5 (SD=10.4) and the majority of patients were female (77.8%). The mean number of years since MS diagnosis was 10.16 (SD=8.23). On average, MFIS scores decreased significantly (BL 12.36+2.18; 12th infusion score 11.16+2.18, p<0.001) and MOS-Cog scores increased significantly over time (BL 25.12+1.51; 12th infusion score 26.19+1.97, p<0.001) after controlling for covariates. **CONCLUSIONS:** MS patients reported improvements in fatigue and overall cognitive function after one year of natalizumab treatment.

PND40

ASSESSMENT OF PERCEIVED SEVERITY OF DISEASE AND SYMPTOMS, QUALITY OF LIFE, WORK PRODUCTIVITY, AND HEALTH CARE RESOURCE USE IN INDIVIDUALS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: There is abundant evidence that individuals with Multiple Sclerosis (MS) have compromised quality of life (QOL) and work productivity, and increased healthcare resource use compared to individuals without MS. The possible association between subjects' self-reported severity of disease and these variables in an MS population has only recently been explored. Patient perceptions of disease have been increasingly recognized as an important factor in healthcare resource use. The objective of this study was to analyze the association between perceived severity of disease (mild, moderate, or severe) and symptoms, quality of life, work productivity, and healthcare resource use in individuals with MS. **METHODS:** Data from respondents reporting an MS diagnosis were obtained from the 2009 National Health and Wellness Survey (NHWS), an Internet-based annual study of the healthcare attitudes and behaviors of a US representative adult sample. The survey included questions about demographics, disease severity, symptoms, quality of life, work productivity, and healthcare resource use. **RESULTS:** In the 2009 NHWS study, 536 reported an MS diagnosis. MS respondents characterized the severity of their disease as follows: mild (n=206; 38.4%), moderate (n=268; 50%); and severe (n=62; 11.6%). There were no differences in the number of years since diagnosis among the groups but there were significantly more men in the severe group. As perceived severity increased among MS patients (mild, moderate, severe), symptom severity generally increased, QOL decreased (SF-12 Physical Component Score), percent with full-time employment decreased, loss of work productivity and presenteeism increased among those reporting employment and healthcare resource use increased (ER visits and hospitalizations). **CONCLUSIONS:** Generally, those with more severe illness reported greater impairment. However, for many of the variables examined, more significant differences were found between patients who perceive their disease severity as mild and moderate than those patients reporting moderate and severe disease severity.

PND41

PARNETING STRESS IN CARING FOR CHILDREN DIAGNOSED WITH NEURO-DEVELOPMENTAL DISORDER

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OBJECTIVES: This study evaluated and examined the relationship between parenting stress in caring for children diagnosed with a neuro-developmental disorder. **METHODS:** A cross-sectional study was conducted by using a self-administered questionnaire distributed through schools that provide services for children with developmental disorder. Parents with children aged 3-18 years and diagnosed with a neuro-developmental disorder were requested to complete the survey. Previously validated scales, the Parenting Stress Index (PSI) and the Columbia Impairment Scale (CIS) were used along with scales to measure parent and child's characteristics. Data was coded and analyzed using SAS v9.2 by performing descriptive and regression analyses. **RESULTS:** A total of 150 surveys were received from 4 schools net response rate (26.5%). The mean parent's age was 45.7(±6.4) years with mothers being higher portion of respondents (84%) and most (90%) were married. Mean PSI reported was 96.9(±23.9) and clinically significant (>85). Higher PSI was attributed to the difficult child (DC) subscale (35.6±10.4) followed by parental distress (PD) subscale (31.8±9.3) and the parent-child dysfunctional interactions (PCDI) subscale (30.2±8.5). Reliability coefficients for the PSI was high (0.91), including the subscales (DC=0.85, PD=0.87, and PCDI=0.8). Mean summary score for CIS was 19.1(±10.7) with a reliability coefficient of 0.9. A multiple regression analysis indicated a positive relationship of PSI with developmental impairment (CIS, β=1.43 p<0.0001) after controlling for child's characteristics (age, gender, diagnosis, number of children, child with similar diagnosis, relationship of parent) and parent's characteristics (age, race, education, employment status, income and existing disorder). **CONCLUSIONS:** Children with severe developmental impairment may lead to greater stress for parents. Untreated stress can cause diseases, such as heart diseases and depression. Interventions controlling stress is the key to improving parents' quality of life for those that care for children with neuro-developmental disorders.

PND42

THE ASSOCIATION BETWEEN PARKININSON'S DISEASE QUESTIONNAIRE (PDQ) SCORES WITH CARER STRAIN AND QUALITY OF LIFE

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OBJECTIVES: The impact of Parkinson's disease (PD) on the quality of life of both patients and their carers has not been well documented. This study describes the health status of both PD patients and caregivers as measured on a generic measure of health status (SF-12), and then explores to what extent patient self-reported health, as measured on the disease-specific Parkinson's Disease Questionnaire (PDQ-39), is associated with carer strain and self-reported quality of life. **METHODS:** A postal survey was carried out of both patients and caregivers through local branches of Parkinson's UK. Questionnaire packs were sent to those on the database with a diagnosis of PD. Patients were asked to give the carer questionnaire to their main caregiver, if they had one. **RESULTS:** Results suggest that PD has substantial adverse effects on both the physical (measured by the Physical Component Summary, PCS) and mental well-being of patients (measured by the Mental Component Summary, MCS) when compared with population norms. Most strikingly PD patients PCS scores fall within the lowest 10% of results, compared with a wider general population sample. While carer physical health was not found to be substantially different from that of the general population, emotional health was severely compromised with a MCS score that places them in the lowest 22% of the population. Regression analysis suggests that the major predictors of carer strain are the PDQ scales of mobility and social support. Carer strain was found to be closely associated with carer mental health. **CONCLUSIONS:** PD impacts on the well being of both patients and caregivers; the data provide evidence that the health status of the patient, in particular their physical health, has a significant impact on the well-being of their caregivers.

PND43

THE PATIENTSLIKEME® EPILEPSY COMMUNITY: A UNIQUE INSIGHT INTO THE LIVES OF PATIENTS WITH EPILEPSY

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OBJECTIVES: To describe key characteristics of members of the online, USA-based PatientsLikeMe® Epilepsy Community, by comparison with a widely-used USA claims database, PharMetrics®, and to assess the impact of epilepsy on patients' lives using patient-reported data, collected through PatientsLikeMe®. **METHODS:** The PatientsLikeMe® Epilepsy Community allows patients with epilepsy to record

their characteristics and monitor treatment and outcomes. The system allows longitudinal entry of well-known Patient Reported Outcome instruments (e.g. QOLIE-31-P, HADS), treatments, symptoms, and seizure frequency and severity. **RESULTS:** By September 2010, 2613 patients had registered; 1838 (70.3%) patients with a reported diagnosis of epilepsy were analyzed. The PatientsLikeMe® Epilepsy Community tends to over-represent females compared with PharMetrics® (71.7% vs. 53.6%) and 20–50 year old patients, reflecting online user demographics. The proportions of treated patients receiving polytherapy or newer AEDs were also greater in PatientsLikeMe® versus PharMetrics® (53.4% vs. 29.2%; 82.4% vs. 66.4%, respectively). Regional coverage of PatientsLikeMe® members appeared closer to US census than PharMetrics®. Patient-reported data from PatientsLikeMe® reflected the significant burden of epilepsy on patients' lives. Patients experiencing ≥1 seizure during the last 4 weeks reported significantly lower quality of life (QoL) and higher levels of depression and anxiety than those not reporting seizures (all p-values <0.005). This was even more pronounced in patients reporting ≥1 generalized tonic-clonic seizure (all p-values <0.001). Driving status was clearly impacted by epilepsy; 50.6% in the PatientsLikeMe® sample did not drive (86.2% of these because of epilepsy) and 37.4% of drivers limited their driving because of epilepsy. Patients with driving limitations reported lower health-related QoL and higher levels of anxiety and depression (all p-values <0.0001). **CONCLUSIONS:** By sharing their records online, members of the PatientsLikeMe® Epilepsy Community provide researchers with a unique source of information. Exploring these data provides insight into the disease burden, treatment patterns and associated outcomes. UCB-sponsored.

PND44

HEALTH-RELATED QUALITY OF LIFE IMPROVEMENTS WITH DYSPORT IN CERVICAL DYSTONIA

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In a multicenter, double-blind trial, Dysport 500 units was compared to placebo in the treatment of cervical dystonia. The primary efficacy response was evaluated using the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS). Pain was evaluated with the Pain subscale of the TWSTRS and a self-reported pain visual analog scale (VAS). HRQL was assessed using the SF-36 Health Survey (SF-36). **OBJECTIVES:** To evaluate improvements in health-related quality of life (HRQL) with in patients with cervical dystonia enrolled in a randomized clinical trial with Dysport™ (also known as abobotulinumtoxinA for Injection in the United States). **METHODS:** Eighty patients were randomly assigned to receive one treatment with Dysport 500 units or placebo. Participants were assessed at baseline and weeks 2, 4, 8, 12, 16, and 20 after treatment. To evaluate HRQL, changes from baseline to Week 8 on the 8 SF-36 domains, the TWSTRS Pain subscale, and the pain VAS were compared. **RESULTS:** TWSTRS total scores were significantly improved with Dysport at weeks 4, 8, and 12 ($P \leq 0.013$ when compared with placebo). Improvements from baseline to week 8 were seen for all 8 SF-36 domains in the Dysport group. The largest improvements occurred in the Role–Physical and Bodily Pain domains. The placebo group showed some decrease (worsening) in Physical Functioning and little to no change in other SF-36 domains. The differences in mean change scores were statistically significant between the Dysport and placebo for 5 of the 8 domains (Physical Functioning, Role–Physical, Bodily Pain, General Health, and Role–Emotional [$P \leq 0.03$ for all]). Improvement in the Bodily Pain domain was also supported by significant improvements in the TWSTRS Pain subscale and the pain VAS at week 4. **CONCLUSIONS:** The data suggest that HRQL is improved with Dysport, particularly pain improvement and in the SF-36 Physical Functioning and Role–Physical domains.

PND45

ONE YEAR OF NATALIZUMAB TREATMENT IS ASSOCIATED WITH AN IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS

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OBJECTIVES: To assess the change in general health-related quality of life (HRQoL) of multiple sclerosis (MS) patients after one year of natalizumab treatment in the usual care setting. **METHODS:** MS patients, newly initiating natalizumab, were recruited to participate in a longitudinal observational study to assess general HRQoL using the SF-12v2 prior to natalizumab initiation (baseline, BL) and after the 3rd, 6th and 12th infusions. Higher physical component summary scores (PCS) and mental component summary scores (MCS) on the SF-12v2 indicate better HRQoL. Statistical regression models were used to evaluate changes in PCS and MCS scores from BL through the 12th infusion after controlling for BL covariates such as age, years since MS diagnosis, number of natalizumab infusions received, disability and functional status, number of MS drugs used prior to natalizumab and comorbidity burden. **RESULTS:** Data for 324 patients who completed the baseline through 12th infusion assessments are reported. The mean age was 46.5 (SD=10.4) and the majority of patients were female (77.8%). The mean number of years since MS diagnosis was 10.16 (SD=8.23). The adjusted PCS score improved significantly from baseline (BL 34.25, 12th infusion 36.66; p<0.001); similar significant improvements were observed in the adjusted MCS scores (BL 43.13, 12th infusion 46.77; p<0.001). **CONCLUSIONS:** Patients reported improvements in general HRQoL measures after one year of natalizumab treatment in the usual care setting. These results are consistent with results from pivotal clinical trials and document the beneficial impact of natalizumab on HRQoL in MS patients.

PND46

THE IMPACT OF EPILEPSY ON ADULT AND PAEDIATRIC PATIENT'S LIVES: A CONCEPTUAL MODEL

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OBJECTIVES: To develop a single conceptual model of the impact of epilepsy on adult and pediatric patients with partial onset seizures to guide the identification of endpoints in clinical trials of new anti-epileptic treatments. **METHODS:** A literature review to identify qualitative research investigating the impact of partial onset seizures on adult and paediatric patients' lives. Structured Embase/Medline searches identified 167 abstracts which were screened to identify primary qualitative research among adult and/or pediatric epilepsy patients. Publications were excluded if they: did not include partial onset seizure patients (with or without generalised seizures); focused on surgical treatment, were not qualitative research; were conducted outside of North America/Europe; focused on epilepsy as a secondary condition. 12 adult and 8 pediatric qualitative studies were identified. Relevant data were extracted into structured tables. Results from both samples were synthesised into a conceptual model by two experienced qualitative researchers. **RESULTS:** Twenty-three concepts were identified from the reviewed literature. Concepts were largely universal between adult and pediatric patients, although content of concepts varied between adults and pediatric, for example paediatric relationship concerns were focused on rejection in friendships and trouble developing relationships. For adults the concerns were problematic relationships with spouse or partner, fulfilling family roles and problems having children. **CONCLUSIONS:** The conceptual model identifies important impacts of epilepsy from the patient perspective. The model also demonstrates areas of patients' lives that may potentially be enhanced through improvement of epilepsy symptoms. As a result, the model allows for concepts of concern to both adult and pediatric patients to be identified and explored as potential patient-reported endpoints in clinical trials of new antiepileptic treatments.

PND47

THE HEMOPHILIA UTILIZATION GROUP STUDY (HUGS-VB): HEALTH-RELATED QUALITY OF LIFE IN HEMOPHILIA B

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OBJECTIVES: To describe health-related quality of life (HRQoL) and health utility of persons with hemophilia B, and to determine the association of these measures with self-reported joint pain and motion limitation. **METHODS:** The prospective, longitudinal Hemophilia Utilization Group Study (HUGS-Vb) recruited participants with hemophilia B from six U.S. Hemophilia Treatment Centers from June 2009 to September 2010. At initial interview, participants or their parent(s) answered questions regarding demographic and clinical characteristics, HRQoL, health utility and self-reported joint pain and motion limitation. HRQoL measures included Short Form-12 (SF-12) for adults and PedsQL for children. Health utility measures used were EQ-5D (adults) and visual analog scale (VAS). **RESULTS:** Seventy-seven participants (48% adults) were recruited. Adult mean SF-12 mental (MCS-12) and physical (PCS-12) component scores were 54.3 (±6.13) and 47.1 (±11.1) respectively. Participants with mild/moderate hemophilia (mean=50.4±9.0) had significantly better PCS-12 scores than those with severe hemophilia (mean=42.6±12.4) (P=0.0390). Mean EQ-5D and VAS scores were 0.85 (±0.16) and 85.5 (±11.1) respectively, with no significant differences between severity groups. PCS-12 and EQ-5D each negatively correlated with self-reported joint pain (PCS-12:P<0.0001, EQ-5D: P=0.0017) and motion limitation (PCS-12:P<0.0001, EQ-5D:P=0.0081); better HRQoL was associated with less severe pain or limitation. Pediatric mean total PedsQL score was 85.6 (±11.2) with physical (PF) and psychosocial functioning summary scores of 92 (±14.9) and 82 (±13.1) respectively. Mean VAS score was 88.6 (±14.3). No significant differences were found between severity groups. PF and VAS scores each negatively correlated with self-reported joint pain (PF:P=0.0127, VAS: P=0.0245) and motion limitation (PF:P=0.0009, VAS:P=0.0015). **CONCLUSIONS:** While previous HRQoL studies have examined hemophilia A and its associated clinical aspects, this is the first focusing on the hemophilia B population. As hemophilia A and B may have different clinical manifestations, HRQoL data on hemophilia B can help define disease burden in this group. One limitation is the current small sample size, which will increase as additional participants continue to be enrolled.

PND48

MEASUREMENT CHARACTERISTICS OF THE SF-36 IN CHRONIC NEUROMUSCULAR DISORDER

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OBJECTIVES: Quality of life (QoL) remains an important consideration in the care of patients presenting with chronic neuromuscular disorder (NMD). The factor structure of the SF-36 was evaluated in patients with NMD in order to determine the appropriateness of this instrument to assess QoL in this clinical population. **METHODS:** Confirmatory factor analyses were conducted on self-report SF-36 data from 245 individual's diagnosed with NMD. Six structural models of the SF-36 were evaluated against data. **RESULTS:** The underlying factor structure of the SF-36 in NMD was observed to be consistent with contemporary theoretical models of the instrument. The traditional measurement model of SF-36, however, performed comparatively poorly. **CONCLUSIONS:** The use of the SF-36 in individuals with